zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

SEP - 2 2011

K110791 (1/2)

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Anthony Francalancia Senior Specialist, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	June 10, 2011
Trade Name:	Bigliani/Flatow® The Complete Shoulder Solution
Product Code / Device:	KWT - Prosthesis, Shoulder, Non-Constrained, Metal/Polymer, Cemented. HSD - Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Uncemented.
Regulation Number / Description:	21 CFR § 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis. 21 CFR § 888.3690 - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Predicate Device:	*Bigliani/Flatow* The Complete Shoulder Solution, manufactured by Zimmer, Inc., K982981, cleared December 17, 1998.
Device Description:	The *Bigliani/Flatow* 56mm Offset Humeral Heads are a line extension to the *Bigliani/Flatow* Shoulder system. The proposed devices are larger diameters of offset humeral heads.
Intended Use:	Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or

	other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable. The humeral component can be implanted either cemented or press-fit while the glenoid component is designed for cemented use only.
Comparison to Predicate Device:	The proposed device is identical to the predicate device in: intended use/indications for use, material specifications, mode of assembly, surface specifications, manufacturing processing, shelf life and sterilization method. The proposed device is a larger size of the predicate device.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing and/or engineering analyses demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing and/or analyses included: Magnetic Resonance Imaging (MRI) Compatibility testing, and Engineering Analysis of proposed offset humeral heads' effect on humeral stem stresses. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Incorporated
% Mr. Anthony Francalancia
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

SEP - 2 2011

Re: K110791
Trade/Device Name: Bigliani/Flatow® The Complete Shoulder Solution
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWT, HSD
Dated: August 18, 2011
Received: August 19, 2011

Dear Mr. Francalancia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110791 (1/1)

Indications for Use

510(k) Number (if known):

Device Name:

Bigliani/Flatow® The Complete Shoulder Solution

Indications for Use:

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights of 27mm or greater may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable. The humeral component can be implanted either cemented or press-fit while the glenoid component is designed for cemented use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110791